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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/079,834	05/15/1998	JOHN D. MOUNTZ	D6005	8770

27851 7590 12/13/2001

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EXAMINER

SPECTOR, LORRAINE

ART UNIT

PAPER NUMBER

1647

22

DATE MAILED: 12/13/2001

Please find below and/or attached an Office communication concerning this application or proceeding.



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This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

### OFFICE ACTION SUMMARY

Responsive to communication(s) filed on 9/24/01

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 1, 3-6, 8, 9, 10-16 is/are pending in the application  
Of the above, claim(s) 10-15 is/are withdrawn from consideration

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 1, 3-6, 8, 9, 16 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims 1, 3-6, 8, 9, 10-16 are subject to restriction or election requirement

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapprove

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been  
received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of Reference Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

**Part III: Detailed Office Action**

**Continued Examination Under 37 CFR 1.114**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. 5 Applicant's submission filed on 6/20/02 has been entered.

Claims 1, 3-6, 8, 9 and 16 are under consideration. No amendment to the claims has been 10 filed since the previous Office Action.

**Objections and Rejections under 35 U.S.C. §112:**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

15 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

20 Claims 1, 3-6, 8, 9 and 16 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of adenoviral vectors AdLoxFasL and Ax CANCre in mice, does not reasonably provide enablement for said vectors in general, particularly in humans. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. This 25 rejection is maintained for reasons of record in paper number 20, mailed 3/23/01, at pages 3-5.

The declaration by Dr. Mountz under 37 CFR 1.132 filed 6/20/02 is insufficient to overcome the rejection of claims 1, 3-6, 8, 9 and 16 based upon 35 U.S.C. § 112, first paragraph as set forth in the last Office action because: The declaration is drawn to results obtained in mouse model

systems, and does not address the primary issue as set forth in paper number 20 at pages 3-4, that the specification does not adequately teach how to practice the claimed invention as the scope of the claims encompasses treatment of humans.

5 Applicants traversal in paper number 26, filed 6/20/02 has been fully considered but is not deemed persuasive.

At pages 2-3 of paper number 26, applicants review the declaration, which is not found persuasive for reasons above. At page 3, applicants further state that "The Examiner has not pointed to any reference or combination of references to support her argument that a person of ordinary skill in this art would not reasonably expect Applicants' claimed method to induce systemic 10 immune tolerance in humans." This argument has been fully considered but is not deemed persuasive because such reasons and citations were clearly set forth in paper number 20, mailed 3/23/01 at paragraphs 10-11.

At page 4, applicants argue that the death of a patient in a University of Pennsylvania gene therapy trial is not relevant to the expectation of success of the instantly claimed invention.

15 This argument has been fully considered but is not deemed persuasive because the point of that citation, as clearly set forth in paper number 20, was that the state of the art is that adenoviral vector studies in mice have not been found in the art to be predictive or results in humans. For example, the action stated in part that "Fox (citation omitted) teaches that the safety characteristics of the adenoviral vector used by the U. Penn researchers (headed by James Wilson) were good, based on 20 studies in mice. Fox also teaches that Wilson indicated that "the doses at which there are toxic effects or potential therapeutic effects may be separated only narrowly, and there may be thresholds where adverse effects abruptly appear- complicating how vectors might be used and perhaps undermining the reliability of results from tests in animals." Accordingly, the state of the art at the time the invention was made was that studies such as those discussed in the specification as 25 originally filed, or in the declaration by Dr. Mountz, were not considered to be predictive of *in vivo* results in humans.

At the paragraph bridging pages 4-5 of paper number 26, applicants state that "It is unlikely

that Applicants' claimed methodology would cause immune system over-reaction and death in a patient as described above." This argument has been fully considered but is not deemed persuasive because (a) applicants have provided no fact or evidence to support this assertion, and (b) the point in citing the results from the University of Pennsylvania study are not to assert that the *same* results would be expected to be obtained, but rather to demonstrate that the state of the art at the time the invention was made was that such mouse studies were not accepted as being predictive of *in vivo* results with humans. It remains that applicants have failed to address the issue of what vectors would be used nor how. Further, as the desired effect of the claimed invention is amelioration (killing) of cells, and as the cells that would be administered would inherently express numerous, multiple antigens, it is not clear on what basis applicants can conclude that no 'over-reaction' could be caused.

It remains that, for reasons set forth in paper number 20, it is not predictable that the claimed invention can be practiced in humans without undue experimentation, and that applicants have provided no facts or evidence to support the predictability of extrapolating their experimental results in mice to humans, especially with respect to the types of vectors and methods to be used, and in view of the recognized lack of predictability in the art, as evidenced by the University of Pennsylvania results. Accordingly, the rejection is maintained.

**Advisory Information:**

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS

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from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be 5 calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10 Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector, whose telephone number is (703) 308-1793. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 5:30 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703)308-4623.

15 Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

20 Certain papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Spector via telephone number 703-746-5228. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

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Lorraine Spector, Ph.D.  
Primary Examiner

LMS  
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9/1/02